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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,063	03/26/2004	William Wold	INGN:106US	8527

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,063	WOLD ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-22,39,40,42,48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-38,41,43-47,49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-49 are pending.

Applicant's traversal and the amendment to claims 23, 28-31 in paper filed on 10/12/06 and the complete listing of claims filed on 12/14/06 is acknowledged and considered by the examiner.

Election/Restrictions

Claims 1-22, 39, 40, and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and lung cancer, prostate cancer, ovarian cancer, testicular cancer, brain cancer, stomach cancer, uterine cancer, breast cancer, esophageal cancer, head & neck cancer, pancreatic cancer, liver cancer, kidney cancer, and blood cancer in claim 25 and 6.7K, RID-alpha, RID-beta, and 14.7K proteins in claim 41 and claim 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/15/06 and 5/2/06.

Claim Objections

Claim 24 is objected to because of the following informalities: the word "cell" is misspelled. Appropriate correction is required.

Applicant did not address the objection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-38, 41, 43-47, and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Wold (US 6,627,190) taken with Walczak (C44).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The patent of Wold is directed to delivering to a tumor (colon) a replication competent adenovirus expressing adenovirus death protein. See column 86 and Figure 4. The adenovirus lacks the gp19k region (column 10). Wold teaches that the ADP coding region is under control of MLP promoter (column 6). Wold teaches that the adenovirus further comprises a mutation in the E1A region, said mutation impairing binding of E1A to p300 and/or pRB (column 86). Wold further teaches combination therapy with radiation (column 12). However, the Wold does not specifically teach expressing TRAIL from the adenovirus vector.

However, at the time the invention was made, TRAIL was known to one of ordinary skill in the art for its tumoricidal activity as taught by Walczak. See page 157. Walczak teaches a plasmid comprising TRAIL. See page 162.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Wold taken with Walczak, namely to express ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching because expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Wold taken with Walczak, namely to use radiation therapy in combination with the adenovirus expressing ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching because expressing radiation therapy and cancer gene therapy are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Wold taken with Walczak, namely to express ADP and TRAIL from the E3 region of the adenovirus. One of ordinary skill in the art would have been motivated to combine the teaching so that ADP and TRAIL are under control of the same promoter.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Wold taken with Walczak, namely to express ADP and TRAIL from the MLP promoter in the E3 region of the adenovirus. One of

ordinary skill in the art would have been motivated to combine the teaching so that ADP and TRAIL are under control of MLP promoter to have expression at the same time.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Wold taken with Walczak, namely to use radiation therapy prior to, same time or after administration of the adenovirus expressing ADP and TRAIL. As a matter of designer's choice, one of ordinary skill in the art would have been motivated to combine the teaching to treat tumors in a mammal. The specification does not display any unexpected results when administering the second therapy prior to, same time, or after administration of the adenovirus.

In view of the teaching of Wold and Walczak, one of ordinary skill in the art would have a reasonable expectation of success for practicing the methods.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made

Applicant's arguments filed 10/12/06 have been fully considered but they are not persuasive.

In response to applicant's argument that US serial no. 09/351,778 to which US patent '190 claims priority to teaches away from using replication competent adenoviral vectors, the argument is not found persuasive because the application for '190 enjoys an earlier priority date before the effective filing date of the instant application. The specification of '190 teaches using replication competent adenoviral vectors.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. One of ordinary skill in the art would have been motivated to combine the teaching of Wold and Walczak to enhance the reduction of tumors in a subject because expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In addition, Wold teaches expressing any protein in telomerase positive in human cancer cells (column 4).

Claims 23-38, 44-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson (US 6,197,293) taken with Griffith et al. (US 6,900,185). Henderson teaches a replication competent adenovirus comprising the adenovirus death protein (ADP) (column 69). Henderson teaches using the adenovirus to treat cancer in humans (columns 1, 17, 29, and 33). Henderson teaches that radiation therapy is used to treat cancer (column 2). Henderson further teaches that some types of cancers are resistant to conventional therapies usually used to treat cancer (column 2). Henderson teaches that ADP can be under control of the E3 promoter or MLP promoter (columns 26-27). Henderson teaches using an additional transgene in the adenovirus (column 27). However, Henderson does not specifically teach expressing TRAIL from the adenovirus.

However, at the time the invention was made, Griffith teaches a method of treating cancer using an adenovirus comprising a promoter operably linked to a transgene encoding TRAIL (column 21). The cancer can be colon cancer (column 21). The cancer can be in a

human (column 22). The method can further comprise administrating a chemotherapeutic agent, radiotherapeutic agent, an immunomodulating agent (column 22).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Henderson taken with Griffith, namely to express ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching for enhancing the treatment of cancer cells in a subject because expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Henderson taken with Griffith, namely to use radiation therapy in combination with the adenovirus expressing ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching because expressing radiation therapy and cancer gene therapy are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Henderson taken with Griffith, namely to express ADP and TRAIL from the E3 region of the adenovirus. One of ordinary skill in the art would have been motivated to combine the teaching so that ADP and TRAIL are under control of the same promoter.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Henderson taken with Griffith, namely to express ADP and TRAIL from the MLP promoter in the E3 region of the adenovirus. One of ordinary skill in the art would have been motivated to combine the teaching so that ADP and TRAIL are under control of MLP promoter to have expression at the same time.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Henderson taken with Griffith, namely to use radiation therapy prior to, same time or after administration of the adenovirus expressing ADP and TRAIL. As a matter of designer's choice, one of ordinary skill in the art would have been motivated to combine the teaching to treat tumors in a mammal. The specification does not display any unexpected results when administering the second therapy prior to, same time, or after administration of the adenovirus.

In view of the teaching of Henderson and Griffith, one of ordinary skill in the art would have a reasonable expectation of success for practicing the methods.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. One of ordinary skill in the art would have been motivated to combine the teaching to enhance the treatment of cancer cells in a subject. The prior art (Henderson, columns 4-5 and Wold US

6,627,190, column 2) teaches that replication competent adenovirus have an advantage over replication defective adenoviral vector in cancer cells.

Applicant's argument with respect to Griffith teaching a replication defective adenovirus comprising a transgene encoding TRAIL is moot because Griffith provides the teaching for delivering a transgene encoding TRAIL to cancer cells. Henderson teaching using an additional transgene in the replication competent adenoviral vector

Applicant argument with respect to Griffith disclosing deleting the entire E1 region of the adenovirus, the argument is moot because claim 43 is not longer rejected under this prior art rejection.

Claims 23 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson (US 6,197,293) taken with Griffith et al. (US 6,900,185) as applied to Claims 23-38, 44-47 and 49 above, and further in view of Bruder et al. (Journal of Virology, 71:7623-7628, 1997).

Henderson taken with Griffith do not specifically teach using the adenovirus, wherein the gp19k region is deleted from the adenovirus.

However, at the time the invention was made, one of ordinary skill in the art understands that the adenovirus gp19K gene product associates with major histocompatibility complex class I proteins and prevents their maturation by sequestering them in the endoplasmic reticulum. The gp19K has been shown to block the ability of adenovirus-specific cytotoxic T lymphocytes to recognize virus-infected cells (page 7623).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Henderson taken with Griffith in further view of Bruder, namely to delete the gp19k region from the adenovirus. One of ordinary skill in the art would have been motivated to combine the teaching so that the mammal's immune system can recognize the adenovirus and assist in killing the tumor cells infected with the adenovirus.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/12/06 have been fully considered but they are not persuasive because the arguments were already addressed in the prior 103(a) rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-26, 32-38, 41, 43-47 and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-75 of copending Application No. 11/057710. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to delivering to a tumor a replication competent adenovirus expressing adenovirus death protein and TRAIL. VRX-013 is used in the instant application working examples and is used in the method of the claims of '710.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 10/12/06 have been fully considered but they are not persuasive for the reasons of record. It is noted that applicant will file a terminal disclaimer if necessary, once either application is allowed.

Claims 23-26, 32-34, 36-38, 41, 43-47 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 6,627,190 in view of Walczak (C44). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to delivering to a tumor a replication competent adenovirus expressing adenovirus death protein. However, the claims from '190 do not specifically teach using expressing TRAIL from the adenovirus vector.

However, at the time the invention was made, TRAIL was known to one of ordinary skill in the art for its tumoricidal activity as taught by Walczak. See page 157. Walczak teaches a plasmid comprising TRAIL. See page 162.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of claims from '190 taken with Walczak, namely to express ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching to enhance the treatment of a tumor in a subject because expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/12/06 have been fully considered but they are not persuasive.

In response to applicant's argument that Wold and Walczak would not lead one to create a single replication-competent adenoviral vector expressing ADP and TRAIL, but instead, would at most suggest the use of two vectors, one for each gene, with the latter being replication-defective, the argument is not found persuasive because in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The only difference between the instant claims and the claims of '190 is the claims from '190 do not recite using an additional transgene in the replication competent adenoviral vector. One of ordinary skill in the art would have been motivated to combine the teaching of Wold and Walczak to enhance the reduction of tumors in a subject because

expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 23-26, 32-38, 41, 43-47 and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-15, 20-22, 24, 32-44, 60-75, and 97-108 of copending Application No. 09/351,778 (C43) in view of Walczak (C44). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to delivering to a tumor a replication competent adenovirus expressing adenovirus death protein. However, the claims from '778 do not specifically teach using expressing TRAIL from the adenovirus vector.

However, at the time the invention was made, TRAIL was known to one of ordinary skill in the art for its tumoricidal activity as taught by Walczak. See page 157. Walczak teaches a plasmid comprising TRAIL. See page 162.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of claims from '778 taken with Walczak, namely to express ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching because expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments filed 10/12/06 have been fully considered but they are not persuasive for the reasons of record. It is noted that applicant will file a terminal disclaimer if necessary, once either application is allowed.

Claims 23-26, 32-38, 41, 43-47 and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-72 of copending Application No. 11/249873 in view of Walczak (C44). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to delivering to a tumor a replication competent adenovirus expressing adenovirus death protein. However, the claims from '873 do not specifically teach using expressing TRAIL from the adenovirus vector.

However, at the time the invention was made, TRAIL was known to one of ordinary skill in the art for its tumoricidal activity as taught by Walczak. See page 157. Walczak teaches a plasmid comprising TRAIL. See page 162.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of claims from '873 taken with Walczak, namely to express ADP and TRAIL from the adenoviral vector in a tumor. One of ordinary skill in the art would have been motivated to combine the teaching because expressing TRAIL and ADP are well known to one of ordinary skill in the art for treating tumors. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments filed 10/12/06 have been fully considered but they are not persuasive for the reasons of record. It is noted that applicant will file a terminal disclaimer if necessary, once either application is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 6:30 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman